Cohort Study to Evaluate Fetal and Infant Outcomes Following Maternal Exposure to Bimekizumab during Pregnancy

First published: 31/07/2026

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Study Planned

Administrative details

EU PAS number

EUPAS1000001042

Study ID

1000001042

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Contact details

Study institution contact

UCB Cares UCBCares@ucb.com

Study contact

UCBCares@ucb.com

Primary lead investigator

Krista Huybrechts

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/12/2022

Actual: 21/12/2022

Study start date

Planned: 01/09/2026

Date of final study report

Planned: 31/12/2035

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

PS0037

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

BIMEKIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC21) bimekizumab

bimekizumab

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes